DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

D1150B

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-39754

January 31, 1997

Arend Van Vliet, Partner
Rock Creek Dairy
29770 E. Hwy. 4
Farmington, CA 95230

WARNING LETTER

Dear Mr. Van Vliet:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on December 17, 1996, by Food and Drug Administration (FDA) Investigator Robert J. Anderson have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On October 4, 1996 you sold a calf (identified by USDA laboratory report number 256411) for slaughter as human food. This calf was delivered for introduction into interstate commerce by your firm and was adulterated by the presence of illegal drug residues. USDA analysis of tissues from this calf revealed tetracycline in the liver at 0.99 parts per million (ppm), and in the kidney at 0.66 ppm. The tolerance level for residues of tetracycline in the edible tissues of cattle has been established at 0.25 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For

example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

You are adulterating the drugs oxytetracycline hydrochloride and neomycin contained in the product Medicated Calf Formula No. 5 you use to medicate your calves within the meaning of Section 501(a)(5) of the Act when you do not use this product in conformance with its approved labeling. Medicated Calf Formula No. 5 labeling specifically states that it is to be used in dry nonmedicated milk replacers only and not in liquid milk as you are doing. Your practice of mixing the product into liquid milk which you feed to your calves, and not maintaining medication records to provide a means to determine proper withdrawal times, is likely the cause of the residues in the calf you sold for food use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt into interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated due to the presence of drug residues. According to USDA analytical reports, during the period of September 16, 1993, through July 27, 1996, your firm offered three other calves and two cows which contained violative levels of antibiotics in

their tissues. You also sold one calf which was found CAST positive . An inspection was conducted of your dairy on December 6, 1989. During that inspection you were warned that it is illegal to market animals with illegal levels of antibiotics. A Regulatory Letter dated, March 1, 1990, was sent to you as a result of the violations found during the inspection. Also, the U.S.Department of Agriculture sent you a letter covering each instance in which their analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act and regulations are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to John M. Reves, Compliance Officer.

Sincerely yours,

Charles D. Moss
Acting Director

for Pat C. Ziobro
District Director
San Francisco District

cc: [redacted]